

FIGURE

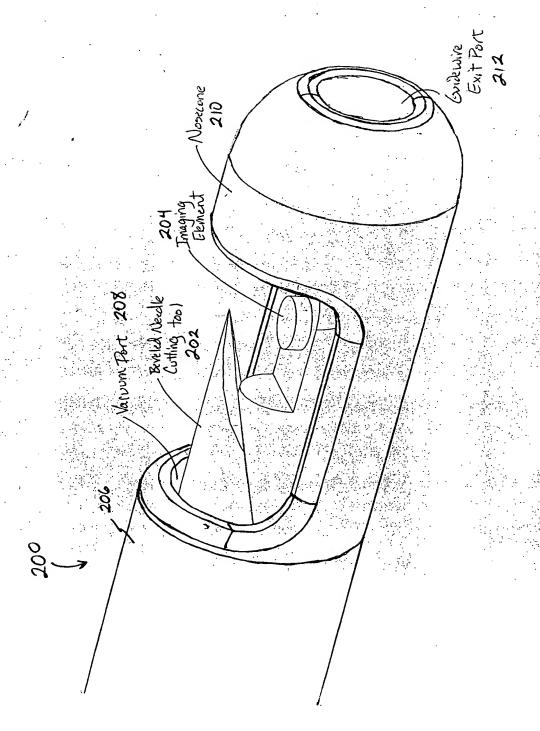


FIGURE 2

FIGURE 3

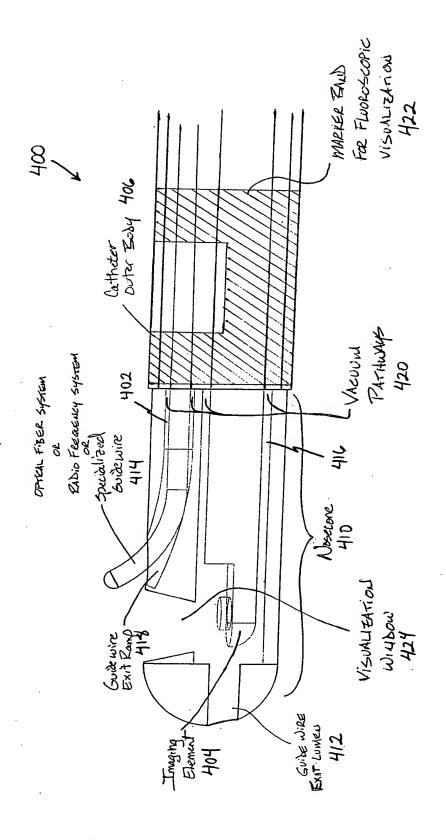


FIGURE 4

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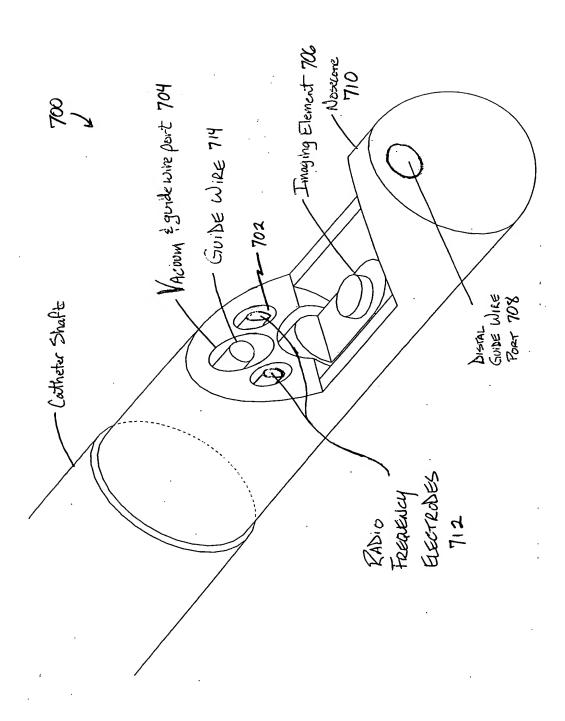


FIGURE 7A

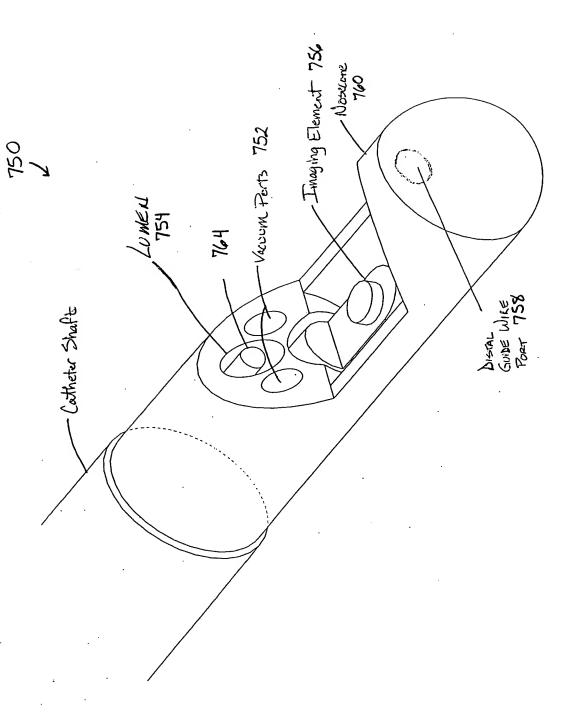


FIGURE 7B

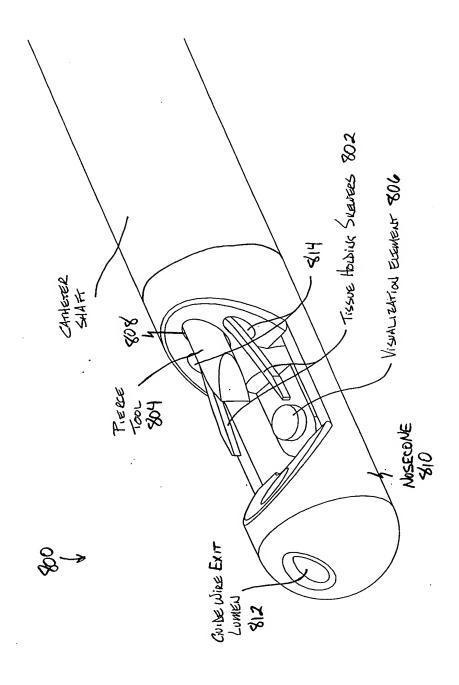


FIGURE 8

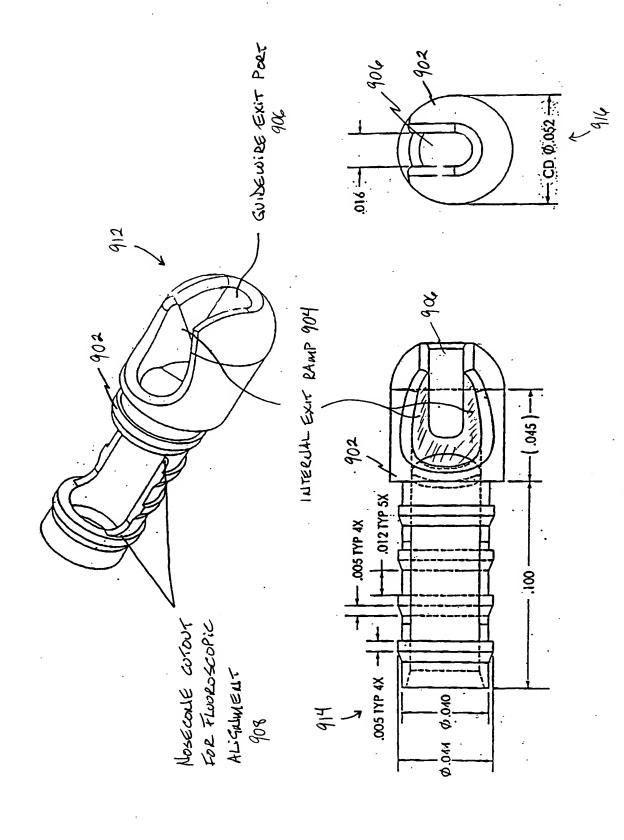
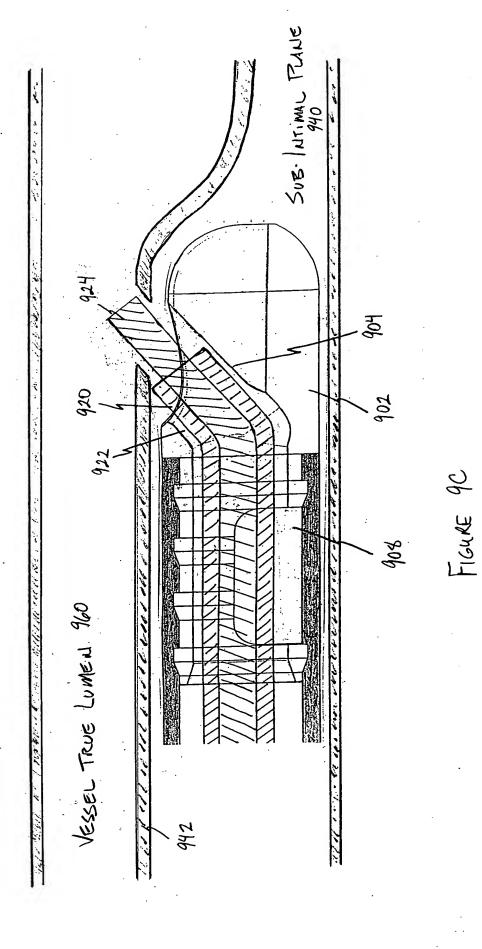


FIGURE 9A

SUB- INTIMAL PLANE 940 INTERNAL EXIT RAMP 40% 950 Vesser Warr Vesser Warr / 950 RE-ENTRY ELEMENTS 924 Vesser TRUE LUMEN 960 CATHETER SHAFF. SUB- LATIMAL T.880R 930

Flaure 96



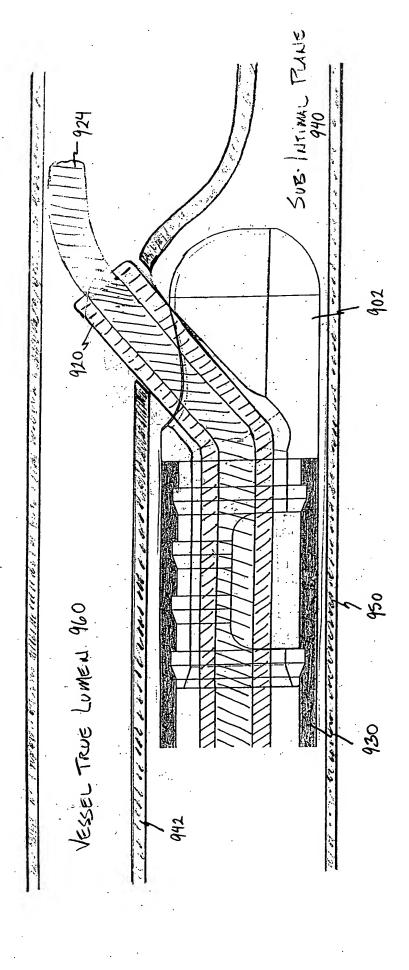
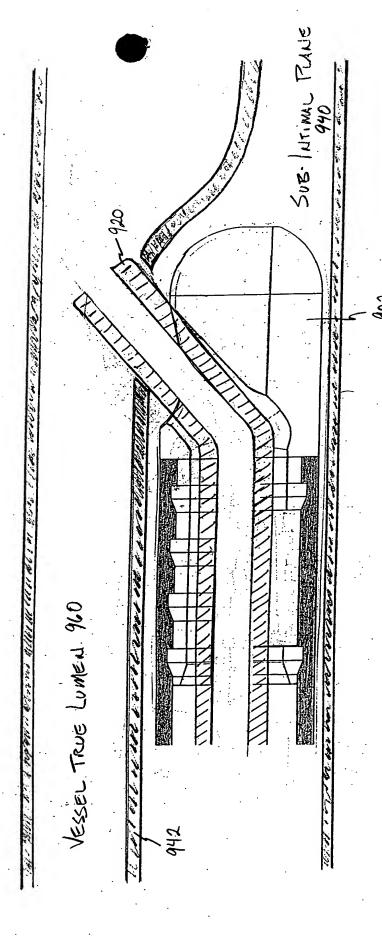


FIGURE 9D



Fleake 9E

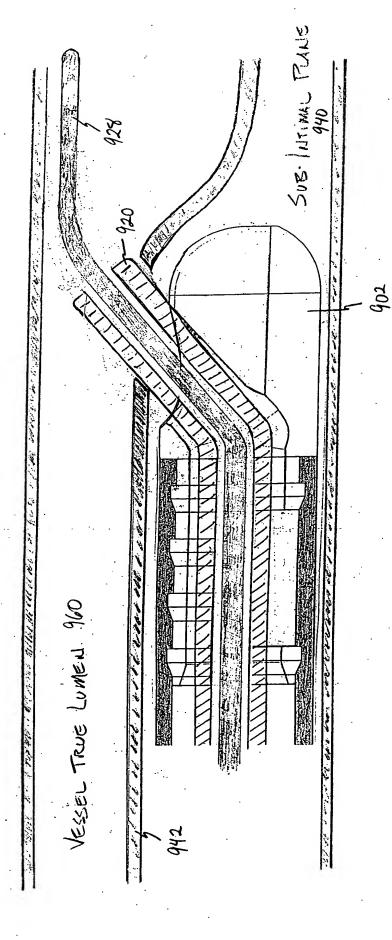


FIGURE 9F

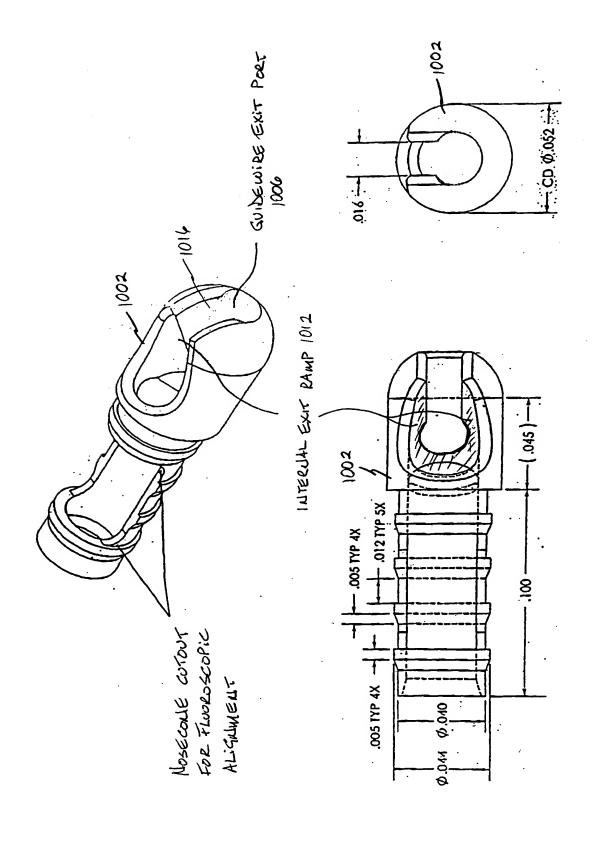
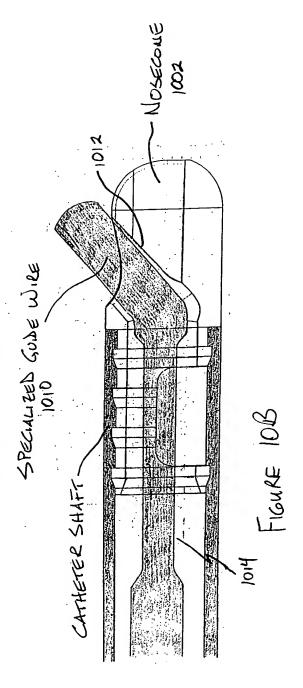


FIGURE 10A



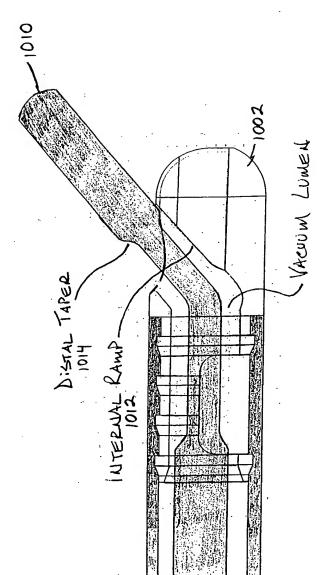


FIGURE 10C

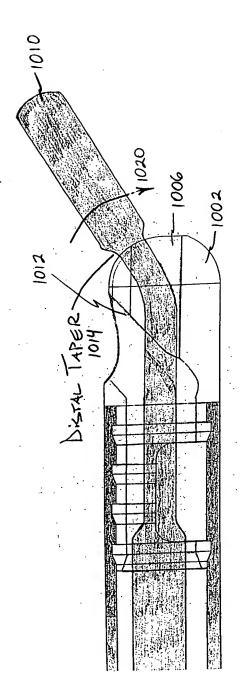


FIGURE 10D

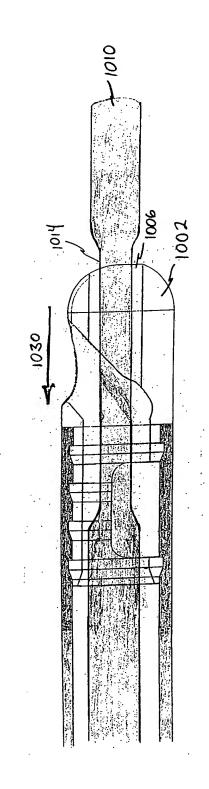
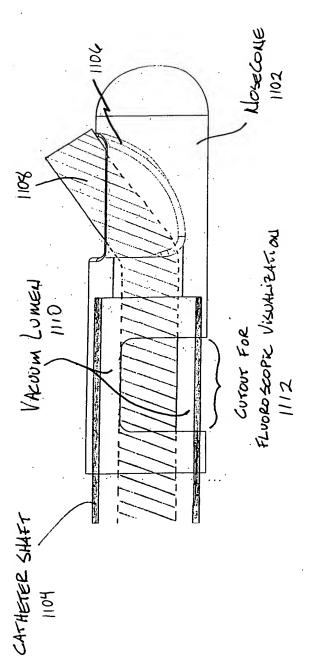


FIGURE 10E





FIGURE

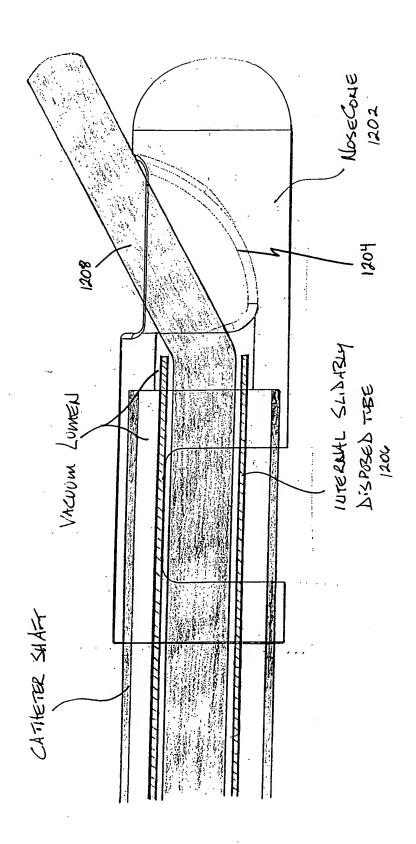


FIGURE 12A

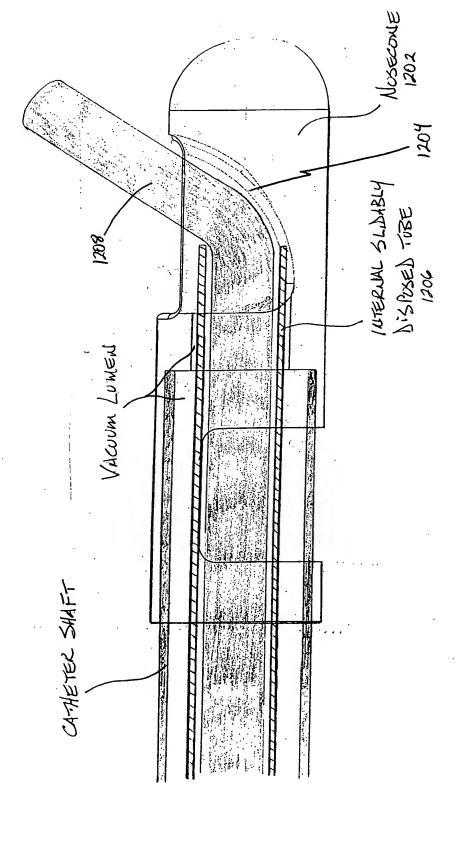


FIGURE 12B

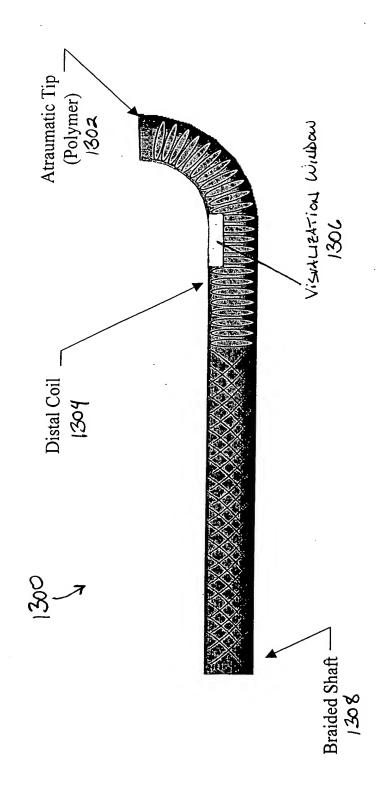


FIGURE 13

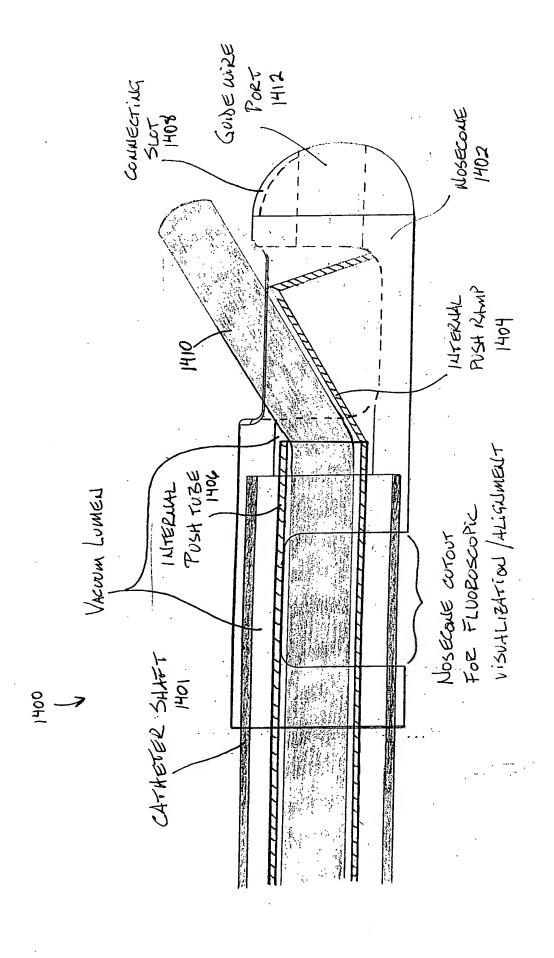
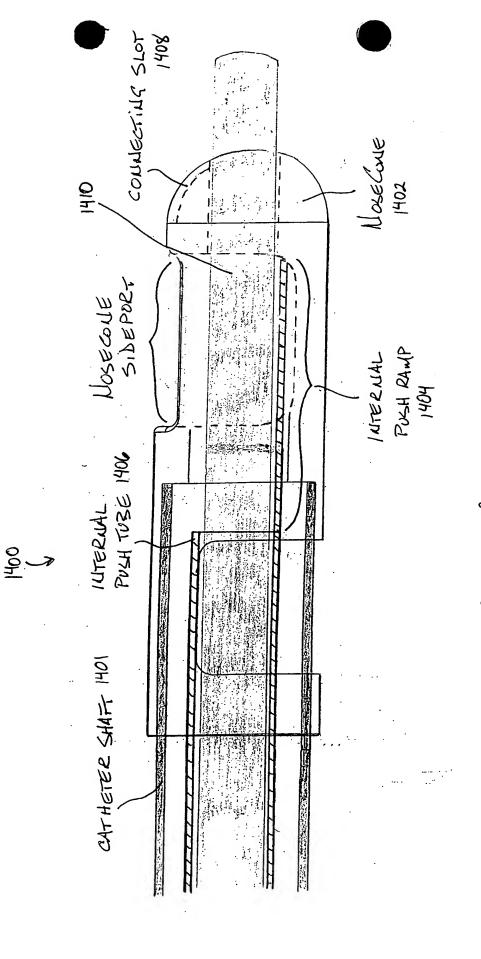


FIGURE 14A



Floure 14B

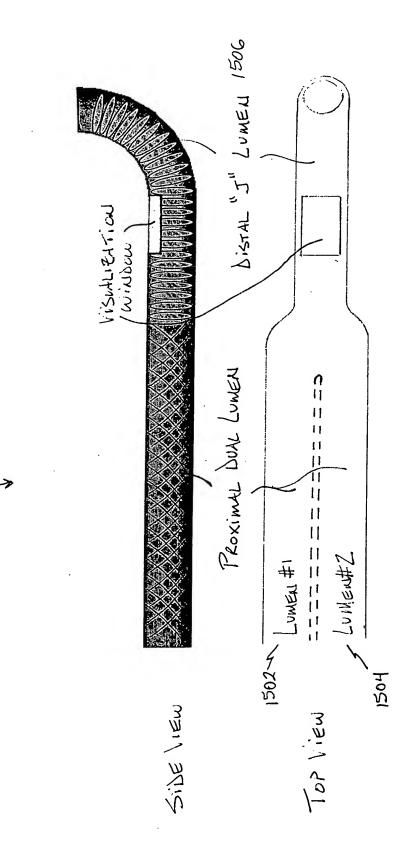


Figure 15

500

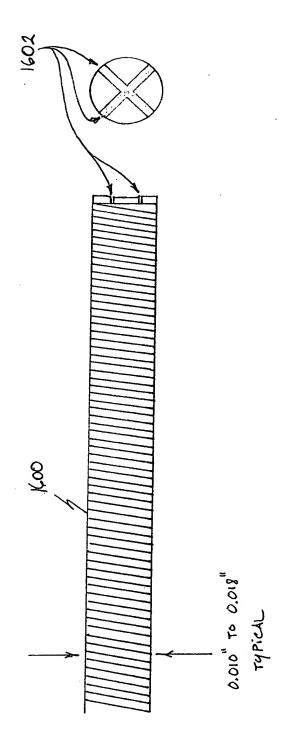


FIGURE 16

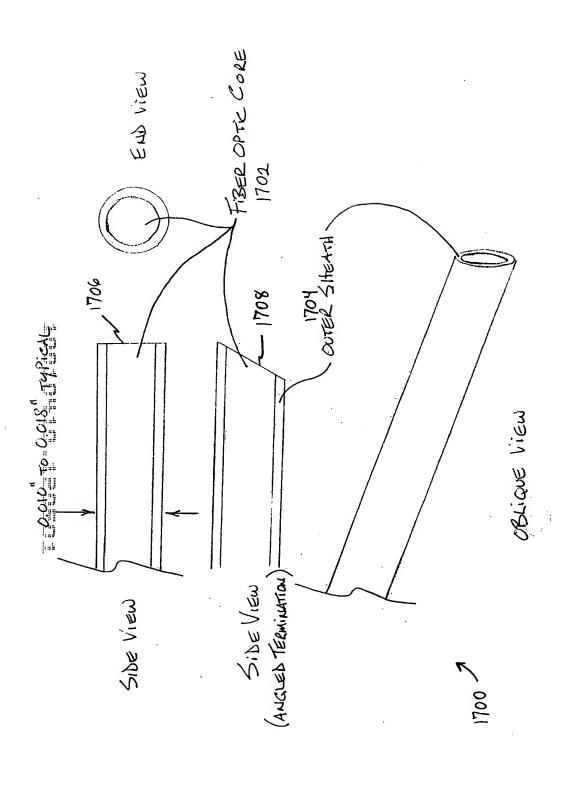


FIGURE 17A

1750

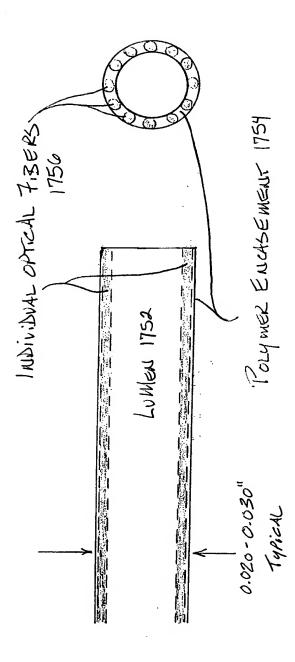
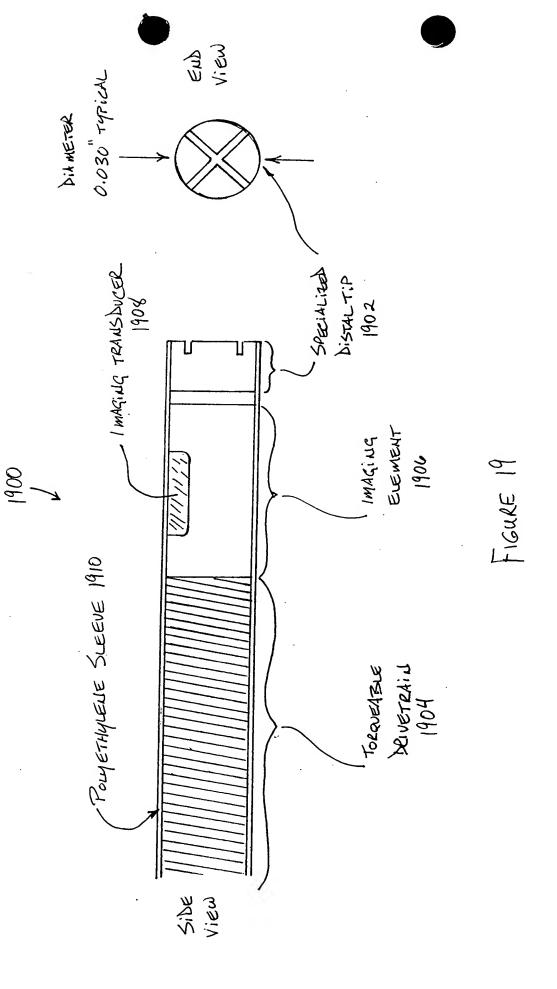


FIGURE 17.B

The state of the s

Floure 18



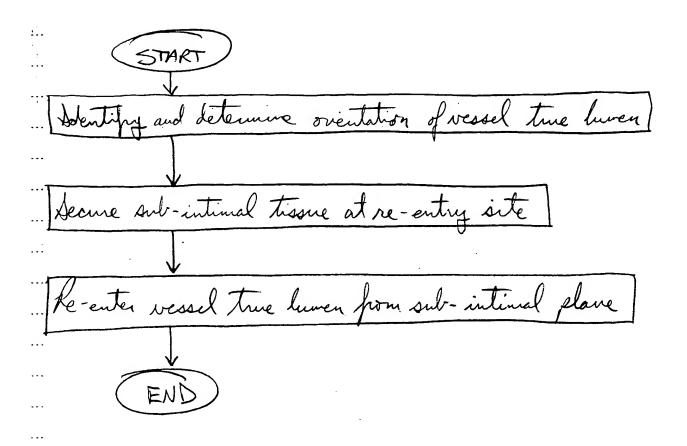


FIGURE 20

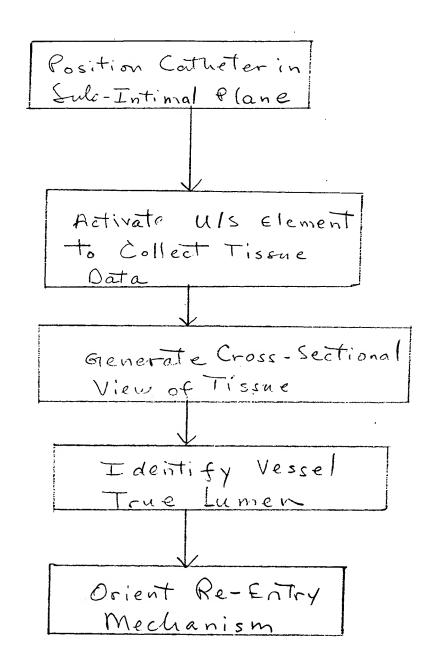


Figure 21

Position Catheter in Sub-Intimal Plane Evacuate Fluids from Sub-Intimal Plane Activate Continuously Rotating System to Collect Tissue Data Genenerate Cross-Sectional View of Tissue Identify Vessel True Lumen Orient Re-Entry Mechanism

Figure 22

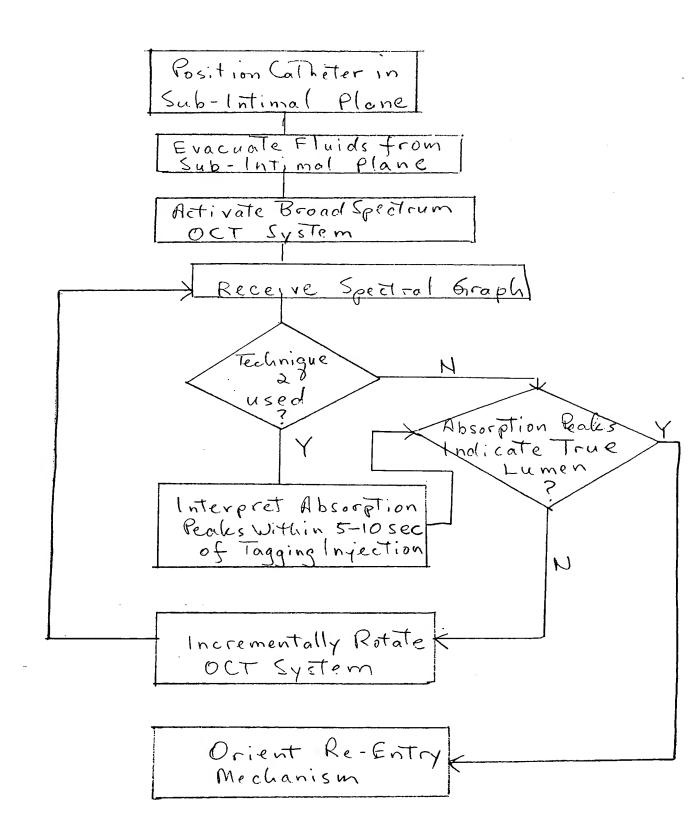


FIGURE 23

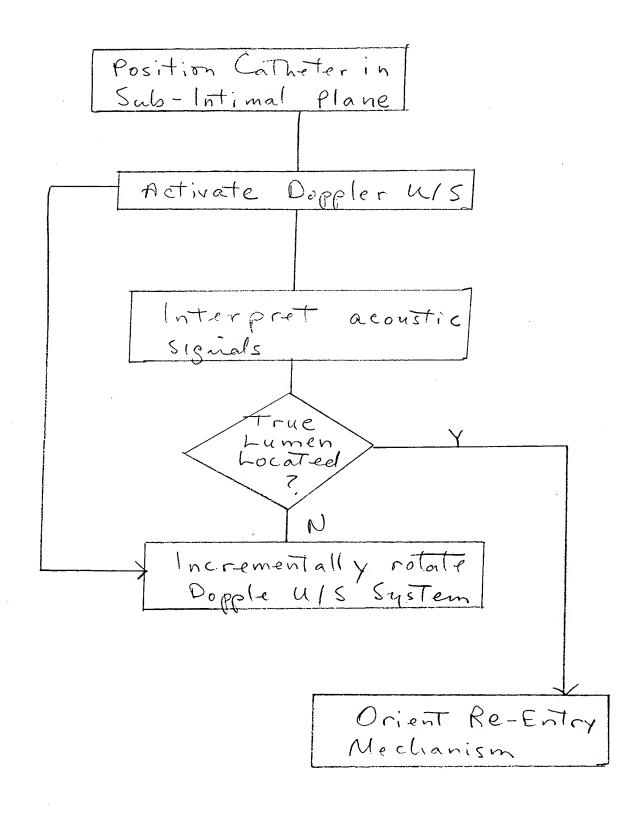


Figure 24

Drieut Re-Entry
Mechanism

Evacuate Sub-Intimal
Plane of Blood and
Fluid

Perform Re-Entry

tigure 26

Orient Re-Entry

Machanism

Evacuate Sub-Intimal

Plane of Blood and

Fluid

Apply Further Vacuum

to Invaginate Tissue

Into Catheter

Perform Re-Entry

Figure 27

Orient Re-Entry Mechanism Evacuate Sub-Intimal Plane of Blood and Fluid Mechanically Secure Sub-Intimal Tissue Against or Inside Nosecone Perform Re-Entry

Figure 28

Position cutting element to cover side por Position catheter in vasculature using guide Texpose side port advance guide wire into True lunes Retract catheter

Position quide wire in sub-intimal space
Retract cannula
Position catheter in vasculature
Position side port with respect to true lumen
Position guide wire proximal to nosecore distal end
Jock sub-intimal tissue onto nosecore surface using vacuum
Using vacuum
advance cannula distally and guide out of side fort via rosecone internal ramps
via rosecone internal ramps
Pierce sub-intimal Tissue
advance guide wire into true lumen
Retract cannula
•

Position guide wire in sub-intimal space Kenove guide wire and load pierce tool Position side post with respect to true lumen Slave sub-intimal tissue using skewers advance sievce tool to pierce pathway throng

Remove guide wire and advance visualization element

Chign side port with respect to vessel true lumen

Jock sub-intimal tissue on surface of catheter using applied vacuum

Push and for votate guide wire distal tipe through put-intimal tissue into vessel true lumen

Position catheter in vasculature using guide wire
Remove guide wire and replace with specialized quick wire
quicle wire
10
activate visualization elevent
١,
Olign side port with respect to vessel time linen
Invaginate sub-intimal tissue into nosecone
· · · · · · · · · · · · · · · · · · ·
Push and for rotate guide were distal tip through sub-intimal Tissue into vessel true lumen
sub-intimal tissue into vessel true lumen

Retract cannula
17
Position catheter in vasculature using guide wire
. Olign side fort with respect to the luner
Position guide wire growing to nosecore distal and
V
Fool sub-internal trasse onto nosecone using vacuum
In secure furchase with sub-intimal tissue
In secure surchase with sub-intimal tissure
Camula distal tip
The same gives were some sign as some sign as
Camula distal lip
· · · · · · · · · · · · · · · · · · ·
Post and/or votate guide wire distal tip through sub-
intimal tissue into vessel true lumen

Position catheter in vasculature with respect to vessel true luner
vessel true lunen
ΛI
advance specialized quide ione proximally relative to distal end of nose cone
Look sub-intimal Tissue onto nosecone using vocuum
V ,
Rotate /advance specialized guick were to engage internal rails of nosecone
internal rails of mosecone
V
Bosh and for votate guide wire distal top through sub- intimal tissue into vessel true luner
intimal lissure into vessel true luney
Advance specialized guice wire further distably until tapered section translates through wisecone slot into moreone distal end port
tapered section translates through mosecone slot into
processore distal end port
1 2 1
Retract catheter

•••
Position catheter in vasculature with respect to vessel true human
vessel true human
\/
Retract guide wire and advance visualization element
, A
Rotate side port to face re-entry site
Ψ
Remove visualization element une advance guide wire
. 11
Lock sub-intimal tissue onto resecone using vacuum
Ordvance guide wire into rosecone until in contact with sub-intimal tissue
with sub-intimal tissue
\/
Push and/or rotate guide wire distal tip through over intimal tissue into vessel the lumen
sob-intimal tissue into vessel the luner
· · · · · · · · · · · · · · · · · · ·
Retract catheter

٠.

	Position guide were appropriately in vasculature
•	
•	Retract push tube
	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
	advance catheter to vascular region of occlusion over the guide wire
	quicle vire
	Control guide wire deployment angle from nose core with position of push tube
	with sosition of such tube
	\ U
	Reloance push tube distally to position quick wire at re-entry site
	re-entry site
• • •	Push guide were through sub-intimal tissue into vessel time lumen
	vessel time lumen
, :	

Load a first lumer with working element
advance catheter over quick wire to wascular region of occlusion using a second human
Retract guide were distal end into satheter, allowing] "I" Tip to re-form
align catheter with respect to re-entry site
Evacuate sub-intimal plane
Establish path into vessel thre luner using working lement
llewent
Retract working element
advance guide vire into vessel time lumen
V V
Retract catteter

first luney with visualization element advance catheter over quide wire to wascu advance insuligation elevent into distal sing align catheter with respect to re-entry site tion element to dual human region Evacuate sub-intimal plane Remove re-entry wire and replace with guide were Retract catheter

FIGURE 41

Position catheter in vasculature using guide wire
Kemove quick wire and advance visualization elevent!
Oliga side port with respect to vessel true lumen
Took white Time To The second while will be
Took sub intimal Tosere on mosecone using vacuum
apply RF energy to electrodes
ablate sub-intimal tissue
D - C + C + C + C + C + C + C + C + C + C
Remove visualization element and replace with guide wire
_ V
Retract catheter

advance cannot dotally along internal raws until in secure purchase with out-intimal Trosure Robrance working element including RF electrodes via cannot to sub-internal tissure Apoly RF energy to electrodes Ablate sub-internal tissure Remove working element and replace with juick wire Advance guide wire into vessel tire luner	
Position catheter in visculature using quick wire Align side port with respect to time lumen Ashrance carried distally along internal range until in secure purchase with sub-intimal tissue Probance working element including RF electrodes via cannula to sub-internal tissue Apoly RF energy to electrodes Ablate sub-intimal tissue Remove working element and replace with guide wire Advance quide wire into vessel tire lunen	Retract cannula
advance cannot dotally along internal raws until in secure purchase with out-intimal Trosure Robrance working element including RF electrodes via cannot to sub-internal tissure Apoly RF energy to electrodes Ablate sub-internal tissure Remove working element and replace with juick wire Advance guide wire into vessel tire luner	
advance cannot dotally along internal raws until in secure purchase with out-intimal Trosure Robrance working element including RF electrodes via cannot to sub-internal tissure Apoly RF energy to electrodes Ablate sub-internal tissure Remove working element and replace with juick wire Advance guide wire into vessel tire luner	Position catheter in vasculature using guide ivere
Advance cannula distally along internal raws until in secure purchase with sub-internal tissue Rebrance working element including RF electrodes via cannula to sub-internal tissue Apoly RF energy to electrodes Ablate sub-internal tissue Remove working element and replace with juide wire Advance guide wire into wessel tire lunen	
Advance cannula distally along internal raws until in secure purchase with sub-internal tissue Rebrance working element including RF electrodes via cannula to sub-internal tissue Apoly RF energy to electrodes Ablate sub-internal tissue Remove working element and replace with juide wire Advance guide wire into wessel tire lunen	align side port with respect to true lunen
Cannula to sub-internal tissue Opply RF evergy to electrodes Whate sub-internal tissue Remove working element and replace with juick wire Advance guide wire into vessel tire lunen	
Cannula to sub-internal tissue Opply RF evergy to electrodes Whate sub-internal tissue Remove working element and replace with juick wire Advance guide wire into vessel tire lunen	advance carriela distally along internal ramp until
Cannula to sub-internal tissue Opply RF evergy to electrodes Whate sub-internal tissue Remove working element and replace with juick wire Advance guide wire into vessel tire lunen	in secure purchase with sub-internal lissue
Apoly Ro evergy to electrodes Ablate sub-intimal tissue Remove working element and replace with juick wire Advance guide wire into vessel thre luner	
Apoly Ro evergy to electrodes Ablate sub-intimal tissue Remove working element and replace with juick wire Advance guide wire into vessel thre luner	Robance working element including RF electrodes via
Apoly Ro evergy to electrodes Ablate sub-intimal tissue Remove working element and replace with juick wire Advance guide wire into vessel thre luner	cannula to sub-internal tissue
Apoly Ro evergy to electrodes Ablate sub-intimal tissue Remove working element and replace with juick wire Advance guide wire into vessel thre luner	
Ablate sub-intimal tissue Remove working element and replace with juick wine Advance guide wire into vessel tire lunen	
Ablate sub-intimal tissue Remove working element and replace with juick wine Advance guide wire into vessel tire lunen	
Remove working element and replace with juick wire and advance guide wire into vessel tire luner	
advance guide wire into vessel tire luncy ?	
advance guide wire into vessel tire luncy ?	Lewove working element and replace with juick wire
· · · · · · · · · · · · · · · · · · ·	
· · · · · · · · · · · · · · · · · · ·	advance guide were into vessel tire luner !
Retract cannula and catheter	
	Retract cannula and catheter

Dit Ht
Position catheter in vasculature using quick were
Retract guide wire and advance visualization dement
Position side port to face re-entry site
Renvox visualization element and advance RF working element
working element
Lock pub-intimal tissue onto nosecone
apply RF energy to electrodes
advance RF working element to ablate sub-
internal tissure
Remove RF working element and replace with quick
wire
V
Advance guide wire into wessel two luver
Retract catheter

Position guide wire in vasculature Ketract push tube advance catheter to vascular region of occlusion over Kenrove guidewire and replace with RF working Control RF working element deployment angle of advance push tube distally to pos RF energy to ablate sub-intin Kenrove RF working element and replace with guide wire advance quick wire into vessel time lumen etract catheter FIGURE 45

Toad optical files system into catheter lunery advance catheter to vascular region of occlusion over Remove guide wire and replace with insualization dedrance optical file system until the distal termination is coincident with lateral exit post alian catheter relative to wased re-entry site apply vacuum to evacuate dissection plane and lock out intend tissue onto catheter surface apply laser energy to optical fiber s ablate sub-internal Tussie at re-entry site Kenove optical fiver system and replace with guide were betrance guide wire into the vessel la FIGURE 46

advance catheter to vascular reg lative to vessel two lumen Evacuate dissection plane us apply laser every to ablate sub Kenrove aptical files system and replace with advance guide wire into true vessel human

Retract cannula
[advance cathotes to vascular site via quick wire]
Oliga catheter relative to vessel time human
Remove guide wire and replace with optical fiber system
Apply vacuum
advance cannula distally for secure purchase with
· ·
Advance optical fiber system until contact is made with
Apply loser energy to ablate sub-intimal tissue
Retract carmila
advance guidewire into true vessel lumen

·
advance catheter to vascular site via quide wire
align catheter relative to vassel time himen
Remove guide wire and replace with optical fiber system
Apply vacuum
advance optical fiber system through nosecore and into contact with sub-intimal tissue
contact with sub-intimal tissue
apply laser energy to ablate sub-intimal Tissue
Remove optical fiber system and replace with guidewire
advance guide were into true vessel lumen
Retact catheter

Posit	ion Catheter in
i	-Intimal Space Using
1 -	de Vire
•	
Alia	u Catheter to Vessel
Tru	e Lumen
Visualization element	method fluoroscopy method
	Rotate Side Port
Advance Visualizat	to face True Lumen
Element Int Nose cone	
100se cone	Remove Guidewire
Activote Visualizar	, = == == = = = = = = = = = = = = = = =
Element	1
Rotate Side Port To	
Face True Lum	en
Patro + Visualia	
Retract Visualiz	41.07
	Advance Sliding Tube to Internal Stop in
	Nose cone Stop in
	Advance Fiber Optic
	System into Sliding Tube
	within 2 cm of Nosecone
FIGURE 50A	Tip
	V

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† † † 1 : :	FROM 50A	•	
•)		
! ::	· · · · · · · · · · · · · · · · · · ·		
	Evacuate fluid	from	
	Sub-Intimal	Plane.	
i		<u> </u>	

1 T	Lock Tissu	ie deur face	
	Outo Nose	cone	
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1.		0 4.	
:	Advance Fib	·	
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! !	Contact wit		
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	Deliver Las) / (
•••	to Optical	fiberto	
	Ablate Ti	ssue	
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	Roleace	Vacuum	
FIGURE Sol			
ii roune De	<i>?</i>		
11.			

Position Guide Wire in Sub-Intimal Spoce Remove Fiber Optic System from Catheter Track Catheter Over Guide Wire visualization element fluorgacopic Guide Wire Remove Rotate Side Port to face True Lumer Advance Visualization Element to Window Remove Guide wire ActivoTe Visualization and Rotate "J" Tip to face True Lumen Element Visualization Remore Advance fiber Optic System Into CoTheter FIGURE SIA

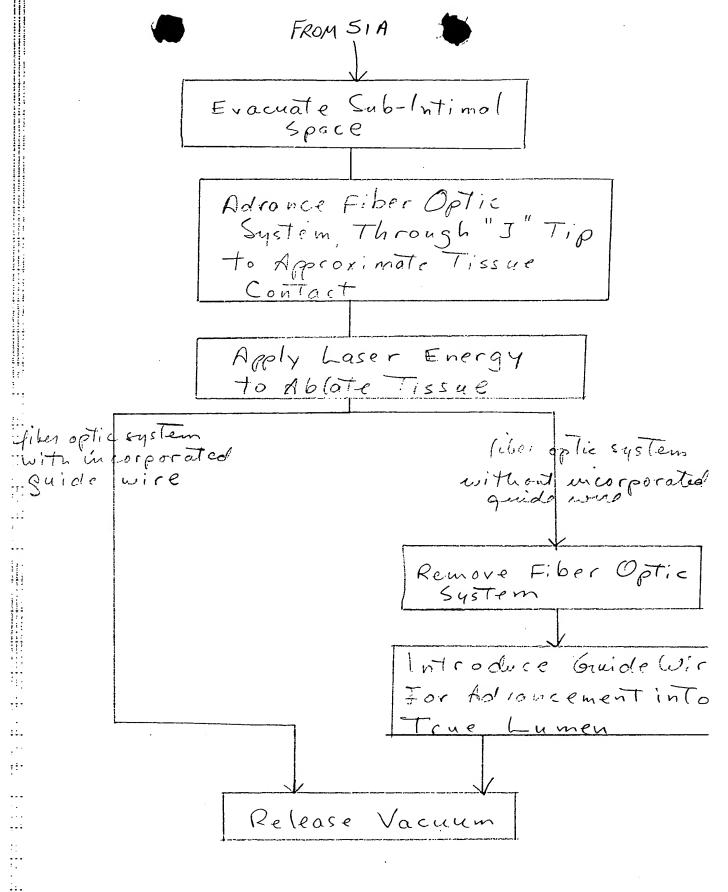


FIGURE 51B

Retract push tube
Idvance catheter to vascular site via quide vire
Olign catheter relative to vessel true luner
Load and advance fiber optic system until proximal to internal ramps
internal ramps
Apply vacuum
V '
adance fiber optic system to contact sub-internal tissue
apply laser energy to ablate sub-intimal tissue
Advance guicle wire into vessel time lumen
Retract push tube so guide were translates through nosecone slot to distal exit fort
nosecone dot to distal exit fort
Remove wacuum
Retract catheter
Floure 52